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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,204	03/06/2001	Ronald Brown Miller	222.94213.CON2	1587

23280 7590 04/23/2002

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EXAMINER

BARTS, SAMUEL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/800,204

Applicant(s)

MILLER ET AL

Examiner

Samuel Barts

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 20-41 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 21-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

DETAILED ACTION

*Election/Restrictions*

1. Applicant's election without traverse of Group I claims 1-19 and 21-41 in Paper No. 5 is acknowledged.

*Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-19 and 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raffa et al (Caplus 1992:120745, J. Pharmacol. Exp. Ther. 1992, 260 (1), 275-85) in view of Bondi (EP 0147780).

Raffa et al teach the use of Tramadol hydrochloride as a pain medicament with opioid and nonopioid properties. The reference teaches Tramadol as a pain medicine working from two different pathways. The instant claimed invention is drawn to oral composition of Tramadol with controlled release features. Some of the claims specifically recite a dissolution rate that is measured by a specific test. The instant claimed invention differs from the prior art by requiring a controlled release composition. The secondary reference of Bondi teaches a controlled release method for a variety of compounds of which Tramadol is listed as an example (see page 7 lines 31-34).

It would have been obvious to one of ordinary skill in the art at the time that applicant's invention was made to have used the controlled release method taught in

Bondi for making an oral composition of Tramadol. Note that Bondi teaches a matrix controlled release system. See for example page 4 lines 1-6. Such a modification would have been obvious because a controlled release composition is the standard and most common way of administering pain medicaments. Thus a skilled artisan preparing the Tramadol for human use would look to use standard controlled release methods such as taught in Bondi.

The claims drawn to specific amounts, specific dosage forms, specific dissolution rates etc., are all obvious since a skilled artisan would reasonably be expected to tweak the controlled release form of Tramadol to meet a variety of needs. For example it is well known that over the counter pain medicines come in countless dosage forms and most come in different controlled release time factors. Pain medicine is typically given in different dosage form depending on such factors as; a) age of patient, b) adult or child c) size and weight of patient, d) particular pain being treated etc.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Barts whose telephone number is 703-308-4630. The examiner can normally be reached on M-F between 6:30am-3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-1235. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-3081235.



Samuel Barts  
Primary Examiner  
Art Unit 1621

s.b.  
April 21, 2002